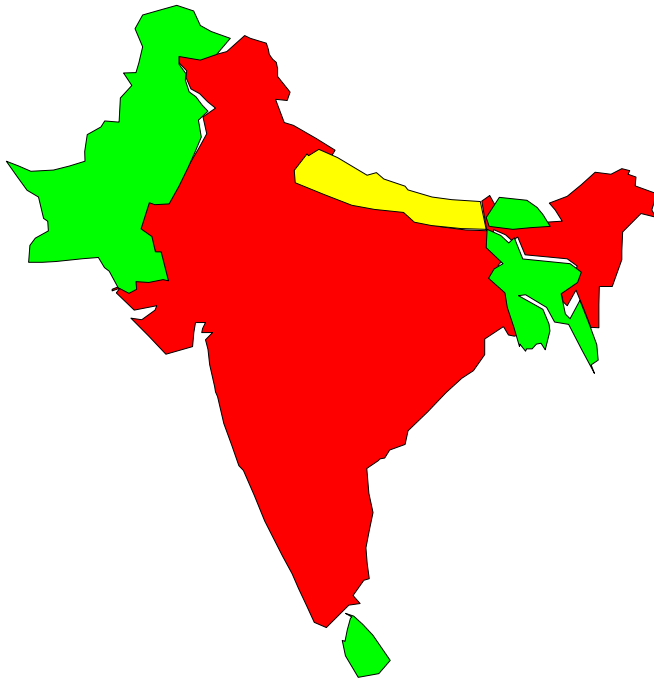


Indian Council of Medical Research

Nandini K Kumar MBBS, DCP, MHSc (Toronto)
Former Deputy Director General Senior Grade (ICMR)
Dr. TMA Pai Endowment Chair, Manipal University

India



- **South East Asia Region**

- Bangladesh
- Bhutan
- India
- Indonesia
- Korea
- Maldives
- Myanmar
- Nepal
- Sri Lanka
- Thailand

Volume and Scope of Research

Population



- 350m in 1947 to 1.30b in Jan.2016
- 2011 Census : growth rate decelerated to 17.64 % in the decade 2001-11
- Heterogeneous Population with different Ethnic Groups and endogamous tribal population with conserved gene pool
- Large no. of treatment naïve persons



- Ancient Civilisation
- Classical Scriptures and Texts for **code** of conduct
- Ethical Guidelines in modern times

Older Codes Of Medical Ethics

- 30th century BC – Siddha
- 10th Century BC – 200 AD : *Caraka Samhita* (written code)
- 4th Century BC : Hippocratic Oath (followed by Modern Medicine & Unani Medicine)

Primum non nocere

DO NO HARM



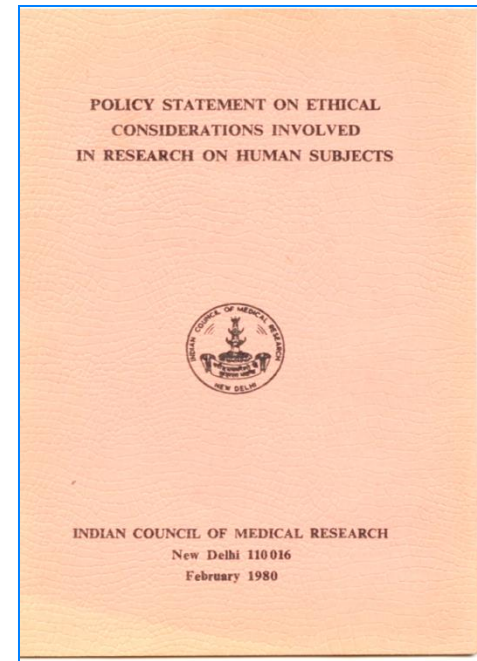
Indian Council of Medical Research

- 1911 – Indian Research Fund Association for funding and co-ordinating research
- 1950 – Renamed as Indian Council of Medical Research
 - 32 Institutes/ Centres
 - 6 Regional Medical Research Centres
 - 70 field stations
- 2007 – Under Department of Health Research of Health Ministry

1980 ICMR Guidelines

“Policy Statement on Ethical Considerations involved in research on Human Subjects

- Ethics Committee
- Informed consent
- Clinical trials
- Research on children, mentally disadvantaged, those with diminished autonomy
- Traditional Medicine
- Publications



1 year after release of Belmont Report

Role of ICMR as National Bioethics Advisory Body

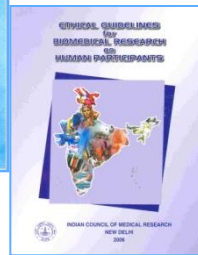
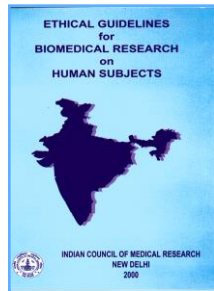
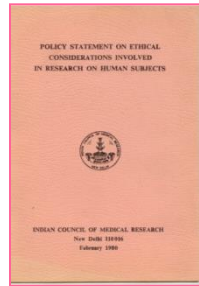
- Central Ethics Committee on Human Research drafted 1st revision of ethical guidelines 2000
- 2000 - After release of guidelines became Central Ethics Committee on Human Research for policy making & reviewing proposals of national significance.

ICMR's Bioethics Cell

Coordinates all activities related to ethical issues pertaining to medical research on humans and animals in India. Its function is as follows:

1. Formulating and revising ethical guidelines
2. Education/ Training in bioethics
3. Consultation on issues related to Bioethics and functioning of Institutional Ethics Committees
4. Coordinating International Collaboration on bioethics

ICMR Guidelines



- 1980 : Policy statement
- 2000 & 2006 : revised ethical guidelines
- 2001 : Indian GCP Guidelines
- 2007 rev. 2013 : ICMR-DBT Guidelines for Stem cell Research & Therapy

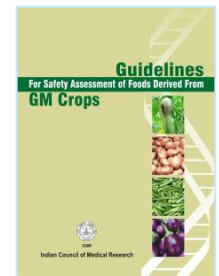
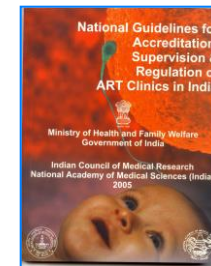
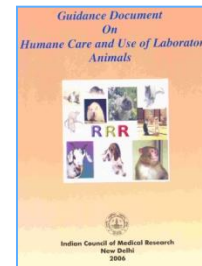
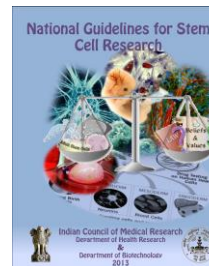
The Bill

**THE BIOMEDICAL
RESEARCH ON HUMAN
PARTICIPANTS
(PROMOTION AND
REGULATION) BILL, 2007**

Title changed to

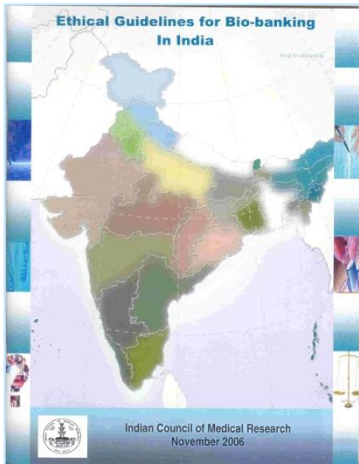
**THE BIOMEDICAL AND
HEALTH RESEARCH
REGULATION BILL**

Legislation in 2016?



Draft ICMR Guidelines

- Biobanking
- Mental Health Research
- Dataset protection
- Research related to disaster situations
- Ethical Guidelines for Research in Children
- Ethical Guidelines for Research in Tribal Groups



ICMR Guidelines Revision 2016

National Ethical Guidelines for Biomedical and Health research on Human Participants

- Statement of General Principles
- General Ethical Issues
- Ethics Review Procedures
- Informed Consent
- Vulnerability
- Clinical Trials
- Epidemiological and Public Health Studies
- Social and Behavioral Sciences
- Human Genetics
- Biobanking and Datasets
- International Collaboration
- New (emerging) Technologies
- Research during Humanitarian Emergency and Disaster
- Responsible conduct of Research

Democracy must in essence, therefore, mean the art and science of mobilising the entire physical, economic and spiritual resources of all the various actions of the people in the service of the common good of all.



Mahatma Gandhi